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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,861	06/24/2003	Kenneth Walter Locke	215233-00400	7200

27160 7590 08/19/2004

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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/601,861

**Applicant(s)**

LOCKE ET AL.

**Examiner**

Taylor Victor Oh

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/24/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____  | 6) <input type="checkbox"/> Other: _____                                    |

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The Status of Claims

Claims 1-10 are pending.

Claims 1-10 have been rejected.

**DETAILED ACTION**

**Priority**

1. None.

**Drawings**

2. The drawings filed on 6/24//2003 are objected by the examiner because figs 1, 1a, and 2-6 are generally unclear as to the numbers ,letters, uneven lines ,and labels on the axes.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-4, and 6-9, the phrase “polymorphic Form A” is recited. This expression is vague and indefinite. The specific PXRD pattern of polymorphic Form A is needed to identify the specific crystalline Form A uniquely different from the other polymorphic forms because the x-ray pattern of a pure crystalline substance can be considered as a “fingerprint” with each crystalline material having within limits, a unique diffraction pattern; furthermore, there are other characteristics to be used in order to distinguish the polymorphic Form A further from the other polymorphic forms, such as bioavailability, solubility, dissolution rate, chemical and physical stability, melting point, color, filterability, density, and flow properties. In addition, the polymorphs are further characterized by other analytical techniques such as differential scanning calorimetry, hot stage optical microscopy, and Raman and infrared spectroscopy. The above techniques are essential tools to be used for identifying “polymorphic Form A” clearly; and it is up to applicants to select which critical parameters may be used so as to establish the unique “polymorphic Form A.”

In claims 1 and 6, the phrase “other polymorphic forms” is recited. This is vague and indefinite because the skilled artisan in the art may wonder what other forms of polymorphs might have been present in the predominant polymorphic Form A. Therefore, an appropriate correction is required.

In claims 2 and 7, the phrase “other polymorphs” is recited. This is vague and indefinite because the skilled artisan in the art may wonder what other forms of

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polymorphs might have been present in the predominant polymorphic Form A.

Therefore, an appropriate correction is required.

In claims 3 , 5, 8 and 10, the term “ substantially” is recited. This is vague and indefinite because the skilled artisan in the art may wonder what is meant by exhibiting “ substantially” a PXRD pattern; for example, it may mean that the PXRD pattern is substantially clear or the representative PXRD pattern is good enough to be distinguished from other PXRD patterns. This expression is uncertain as to how much the representative PXRD pattern has been revealed in the X-ray diffraction. Therefore, an appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Myer ✓ on*  
*8/16/54*

*Chalia Tsay*  
Supervisory Patent Examiner  
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